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DONALD ELLIS

A 1902636

vs.

ABBOTT LABORATORIES

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DEMAND**

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VERIFY RECORD

**COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO**

This Document Relates To:

DONALD ELLIS
1790 Lovers Lane
New Lexington, OH 43764

Plaintiff,

vs.

ABBOTT LABORATORIES
100 Abbott Park Road
Abbott Park, Illinois 60064

**ASTRAZENECA PHARMACEUTICALS
LP**
1800 Concord Pike
Wilmington, Delaware 19850

ASTRAZENECA LP
1800 Concord Pike
Wilmington, Delaware 19850

**MERCK & CO., INC. D/B/A MERCK,
SHARP & DOHME CORPORATION**
One Merck Drive
Whitehouse Station, New Jersey 08889

PFIZER, INC.
235 East 42nd Street
New York, New York 10017

THE PROCTER & GAMBLE COMPANY
1 Procter & Gamble Plaza
Cincinnati, Ohio 45202

CASE NO:

Judge

**COMPLAINT WITH JURY
DEMAND ENDORSED HEREON**

**THE PROCTER & GAMBLE
MANUFACTURING COMPANY**
3875 Reservoir Road
Lima, Ohio 45801

**TAKEDA PHARMACEUTICALS USA,
INC.**
One Takeda Parkway
Deerfield, Illinois 60015

**TAKEDA PHARMACEUTICALS
AMERICA, INC.**
One Takeda Parkway
Deerfield, Illinois 60015

**TAKEDA DEVELOPMENT CENTER
AMERICAS, INC. F/K/A TAKEDA
GLOBAL RESEARCH &
DEVELOPMENT CENTER, INC.**
One Takeda Parkway
Deerfield, Illinois 60015

**TAKEDA PHARMACEUTICAL
COMPANY LIMITED**
1-1, Doshomachi 4-chome
Chuoku, Osaka, Japan

Defendants.

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COMES NOW, Plaintiff(s), Donald Ellis, by and through the undersigned counsel, and brings this Complaint against Abbott Laboratories; AstraZeneca Pharmaceuticals LP (“AZ Pharm”); AstraZeneca LP (“AZ LP”); GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (“GSK LLC”); Merck & Co., Inc. d/b/a Merck, Sharp & Dohme Corporation (“Merck”);

("PGM"); Takeda Pharmaceuticals USA, Inc. ("TPUSA"); Takeda Pharmaceuticals America, Inc. ("TPA"); Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. ("TDC Americas"); Takeda Pharmaceutical Company Limited ("TPC"), hereinafter collectively referred to as "Defendants" and for their Complaint and Jury Demand allege as follows:

NATURE OF THE ACTION

1. Plaintiff seeks compensatory and punitive damages, monetary restitution and all other available remedies as a result of injuries caused by Defendants' defective pharmaceutical products. Plaintiff makes the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys' investigative efforts to date, regarding Defendants' prescription and over-the-counter Proton-Pump Inhibitor products (hereinafter together or individually, "the PPI Products" or "PPIs").

2. The Plaintiff herein does not relinquish the right to move to amend his individual claims to seek any additional claims as discovery proceeds and facts and other circumstances may warrant.

3. As more particularly set forth herein, the plaintiff maintains that the PPI Products are defective in design, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lack proper warnings associated with their use.

4. This is a personal injury action against Defendants and their affiliates, subsidiaries, alter-egos, and/or joint venturers who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling the PPI Products, including, but not limited to Nexium, Prevacid, Prilosec, and Prilosec OTC.

5. PPI Products are used to suppress the production of acid in order to reduce the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as to treat

including Zollinger-Ellison syndrome.

PARTIES, JURISDICTION & VENUE

6. Plaintiff, respectively, alleges an amount in controversy in excess of the minimal jurisdictional limits of this Court. The amount in controversy exceeds TWENTY- FIVE THOUSAND DOLLARS (\$25,000.00), exclusive of interest and costs, the jurisdictional minimum of this Court.

I. PLAINTIFF

7. Plaintiff, Donald Ellis, resides in New Lexington, Ohio and resided in New Lexington, Ohio at all times relevant.

- a. Plaintiff, Donald Ellis ingested the following PPI products sold by the Defendants from at least approximately August 2009 to February 2018:
Nexium, Prevacid, Prilosec, and Prilosec OTC.
- b. As a direct and proximate result of Plaintiff's use of the PPI(s), Nexium, Prevacid, Prilosec, and Prilosec OTC, Plaintiff has suffered and was treated for an Acute Kidney Injury ("AKI") in approximately February 2017 and Chronic Kidney Disease ("CKD") in approximately September 2017 with related sequelae.

II. DEFENDANTS

8. Defendant Abbott Laboratories ("Defendant Abbott") is and, at all times relevant to this action, has been an Illinois Corporation having a principal place of business at 100 Abbott Park Rd., Abbott Park, Ill. 60064.

involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription Prevacid (lansoprazole) products.

10. Defendant Abbott manufactures and markets Prevacid in the United States.

11. Defendant Abbott has transacted and conducted business related to Prevacid in each of the States and Territories of the United States.

12. Defendant Abbott has derived substantial revenue from Prevacid in each of the States and Territories of the United States.

13. Defendant Abbott has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid.

14. Defendant AstraZeneca Pharmaceuticals LP (“AZ Pharm”) is and, at all times relevant to this action, has been a Delaware limited partnership having a principal place of business at 1800 Concord Pike, Wilmington, DE 19850.

15. Defendant AstraZeneca LP (“AZ LP”) is, and at all times relevant to this action, has been a limited partnership organized under the laws of Delaware having a principal place of business in Delaware, whose ultimate parent company is AstraZeneca PLC.

16. Defendants AZ Pharm and AZ LP are referred to collectively herein as “AZ Defendants.”

17. Each of the AZ Defendants was the agent and employee of the other AZ Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other AZ Defendants’ actual and implied permission, consent, authorization and approval.

18. The AZ Defendants, in collaboration amongst themselves, designed, tested, researched and developed the prescription and non-prescription over-the-counter Prilosec (omeprazole) and Nexium (esomeprazole) products.

19. As a part of their business and at all relevant times, the AZ Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of both prescription and over-the-counter Prilosec and Nexium products.

20. In 1982, the AZ Defendants entered a joint venture with Defendant Merck to design and develop the first proton pump inhibitor.

21. The result of this joint-venture was the development of omeprazole, which was ultimately marketed and sold under the brand name Prilosec.

22. In September 1989, the FDA approved Prilosec for healing of erosive esophagitis, maintenance of healing erosive esophagitis and treatment of GERD.

23. The AstraZeneca Defendants hold and have held the patent for the drug Prilosec which, by the year 2000, was the most widely prescribed drug in the world.

24. In an agreement reached in 1997, the AstraZeneca Defendants licensed to the Procter & Gamble Defendants the exclusive rights to market the over-the-counter version of Prilosec, known as Prilosec OTC, which was launched in September 2003.

25. According to the agreement between the Procter & Gamble Defendants and the AstraZeneca Defendants, the AstraZeneca Defendants supply Prilosec OTC and the Procter & Gamble Defendants market and sell Prilosec OTC.

26. In an agreement reached in December 1997, the AstraZeneca Defendants entered into a co-promotion agreement with the Procter & Gamble Defendants granting the Procter & Gamble Defendants the right to market Prilosec.

27. According to the agreement between the Procter & Gamble Defendants and the AstraZeneca Defendants, the AstraZeneca Defendants supply Prilosec and the Procter & Gamble Defendants market and sell Prilosec.

28. In 2006, the FDA approved New Drug Application (“NDA”) 22056 to allow the AstraZeneca Defendants the right to market and sell prescription Prilosec to children aged two and younger for the treatment of GERD.

29. Defendant AZ Pharm is the holder of approved NDA 019810 for Prilosec Delayed-Release Capsule Pellets and 022056 for Prilosec Delayed-Release Oral Suspension.

30. Defendant AZ LP is the holder of NDAs 019810/S-1 – S-102 for Prilosec Delayed Release Capsules, 022056/S-1-S-019 for Prilosec delayed release oral suspension and 021229/S-1-S-029 for Prilosec OTC delayed release tablets.

31. The AZ Defendants manufacture and market each of these Prilosec formulations in the United States.

32. In anticipation of the expiration of the patent for prescription Prilosec, the AZ Defendants launched an internal program called Operation Shark Fin for the purpose of developing a second PPI Product in order to capitalize on the market for PPI Products. The result of Operation Shark Fin was the development of Nexium (esomeprazole).

33. In December 1999, Defendant AZ Pharm submitted its first NDA for a Nexium product, NDA 021153, to the FDA for approval to market Nexium in the United States.

34. In December 2000, the FDA simultaneously approved Nexium, NDA 021153, and Nexium Delayed Release, NDA 021154, for healing of erosive esophagitis, maintenance of healing erosive esophagitis, treatment of symptomatic GERD and H. pylori eradication to reduce the risk of duodenal ulcer recurrence (as part of a triple therapy with amoxicillin and clarithromycin).

35. Defendant AZ Pharm is also the holder of approved NDAs 021937 and 022010 for Nexium Delayed-Release Oral Suspension, and NDAs 022101 and 021689 for Nexium Injection Solution.

36. The AZ Defendants manufacture and market each of the aforementioned Nexium formulations in the United States.

37. In 2003, the AZ Defendants spent \$260 million alone in promoting and marketing Nexium products to American consumers, the largest amount spent on marketing a single brand of pharmaceutical to that date.

38. The AZ Defendants have transacted and conducted business related to PPI products in each of the States and Territories of the United States.

39. The AZ Defendants have derived substantial revenue from PPI Products used in each of the States and Territories of the United States. For example, in 2003 alone, sales of Nexium in the United States was \$2.7 billion and world-wide was \$3.9 billion.

40. The AZ Defendants have expected or should have expected their acts to have consequences within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPIs.

41. Defendant Merck & Co. Inc. d/b/a Merck, Sharp & Dohme Corporation (hereinafter “Defendant Merck”) is and, all times relevant to this action, has been a New Jersey corporation having a principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

42. In 1982, Defendant Merck entered into an agreement with the AZ Defendants, under the terms of which Defendant Merck developed and marketed the AZ Defendants’ products, including Nexium and Prilosec products, under a royalty-bearing license.

43. In 1993, Merck’s total sales of the AstraZeneca Defendants’ products reached a level that triggered the first step in the establishment of a joint venture business (the “Joint

This Joint Venture, formed in 1994, was called Astra Merck Inc. and was responsible for the sale of Prilosec and other of the AstraZeneca Defendants' products.

44. In 1997, the Procter & Gamble Defendants formed a strategic alliance with the Joint Venture to develop and market Prilosec OTC.

45. Until 2014, Defendant Merck had a contractual and ownership interest in the Joint Venture. Through these interests, between 2009 and 2014, Defendant Merck earned at least \$7 billion, based on the sales of prescription and over-the-counter formulations of Nexium and Prilosec.

46. Defendant Merck currently has, and will continue to have until 2018, a financial interest in prescription and over-the-counter formulations of Nexium and Prilosec.

47. As a part of their business and at all relevant times, Defendant Merck has been and is involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription and over-the-counter formulations of Prilosec and Nexium.

48. In 1989, Defendant Merck sponsored the first NDA for a Prilosec product, NDA 019810, which it submitted to the FDA for approval to market Prilosec. Under this NDA the following forms of Prilosec have been approved: Delayed-Release Capsule Pellets (20mg), approved on September 14, 1989; Delayed-Release Capsule Pellets (10mg), approved on October 5, 1995; and Delayed-Release Capsule Pellets (40mg) approved on January 15, 1998.

49. Defendant Merck has also had a contractual, ownership and financial interest in Prilosec Delayed-Release Oral Suspension, NDA 022056.

50. Defendant Merck, through the Joint Venture, also designed, researched, manufactured, tested, advertised, marketed, sold and distributed Nexium.

51. Defendant Merck has had a contractual, ownership and financial interest in the following FDA approved forms of Nexium: Delayed-Release Capsule Pellets, NDA 021153;

Solution, NDA 021689.

52. Defendant Merck manufactures and markets Nexium products in the United States.

53. Defendant Merck manufactures and markets Prilosec products in the United States.

54. Defendant Merck has transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

55. Defendant Merck has derived substantial revenue from PPI Products in each of the States and Territories of the United States.

56. Defendant Merck has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

57. Defendant The Procter & Gamble Company is and, all times relevant to this action, has been an Ohio corporation with its principal place of business at 1 Procter & Gamble Plaza, Cincinnati, OH 45202.

58. Defendant The Procter & Gamble Manufacturing Company is and, all times relevant to this action, has been an Ohio corporation with its principal place of business at 3875 Reservoir Road, Lima, OH 45801.

59. Defendant The Procter & Gamble Distributing LLC f/k/a The Procter & Gamble Distributing Co. is and, at all times relevant to this action, has been an Ohio corporation with its principal place of business at 6280 Center Hill Ave., Cincinnati, OH 45224.

60. At all times relevant to this action Defendant The Procter & Gamble Company has been the direct or indirect owner of substantially all of the stock or other ownership interests

Manufacturing Company.

61. Defendant The Procter & Gamble Company, Defendant The Procter & Gamble Distributing LLC and Defendant The Procter & Gamble Manufacturing Company are referred to collectively herein as the “Procter & Gamble Defendants.”

62. Each of the Procter & Gamble Defendants was the agent and employee of the Other Procter & Gamble Defendant, and in doing the things alleged were acting within the course and scope of such agency and employment and with the other Procter & Gamble Defendant’s actual and implied permission, consent, authorization and approval.

63. The Procter & Gamble Defendants, in collaboration amongst themselves and the AstraZeneca Defendants, designed and developed Prilosec OTC.

64. As a part of their business and at all relevant times, the Procter & Gamble Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prilosec OTC.

65. In or about 1997, Defendant The Procter & Gamble Company entered into a marketing agreement with Defendant AstraZeneca LP whereby the Procter & Gamble Defendants acquired the rights to market Prilosec OTC products.

66. On or about January 27, 2000, Defendant The Procter & Gamble Company, in collaboration with and pursuant to its marketing agreement with Defendant AstraZeneca LP, submitted NDA 021229 for Prilosec OTC delayed release tablets.

67. On or about June 20, 2003, Defendant The Procter & Gamble Company, in collaboration with and pursuant to its marketing agreement with Defendant AstraZeneca LP, was granted approval for NDA 021229, Prilosec OTC.

68. The Procter & Gamble Defendants made Prilosec OTC available for purchase in the United States on or about October 2003 and continue to manufacture and market each formulation of Prilosec OTC in the United States.

69. In or about December 8, 1997 Defendant The Procter & Gamble Distributing LLC, in collaboration with and pursuant to a co-promotion agreement with AstraMerck, Inc., acquired the right to market Prilosec.

70. The Procter & Gamble Defendants, in collaboration amongst themselves and the AstraZeneca Defendants, co-promoted Prilosec from at least December 8, 1997 until the co-promotion agreement was terminated on January 12, 2001.

71. The Procter & Gamble Defendants have transacted and conducted business related to Prilosec OTC in each of the States and Territories of the United States.

72. The Procter & Gamble Defendants have derived substantial revenue from Prilosec OTC in each of the States and Territories of the United States.

73. The Procter & Gamble Defendants have expected or should have expected their acts to have consequences within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prilosec OTC.

74. Defendant Takeda Pharmaceuticals USA, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

75. Defendant Takeda Pharmaceuticals America, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

76. Defendant Takeda Pharmaceuticals, LLC, at all times relevant to this action, has been wholly owned by Defendant Takeda Pharmaceuticals America, Inc. and Defendant Takeda Pharmaceuticals USA, Inc.

77. Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, IL

78. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

79. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been the parent/holding company of Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

80. Defendant Takeda Pharmaceutical Company Limited, at all times relevant to this action is a parent company and has exercised and exercises dominion and control over Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

81. Defendant Takeda Pharmaceuticals USA, Inc., Defendant Takeda Pharmaceuticals America, Inc., Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. and Defendant Takeda Pharmaceutical Company Limited are referred herein collectively as “Takeda Defendants.”

82. Each of the Takeda Defendants was the agent and employee of the other Takeda Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other Takeda Defendants’ actual and implied permission, consent, authorization and approval.

83. As a part of their business and at all relevant times, the Takeda Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid products.

84. The Takeda Defendants, in collaboration amongst themselves, designed and developed the Prevacid products.

020406, 021428 and 021281 for Prevacid.

86. The Takeda Defendants manufacture and market each of these prescription Prevacid formulations in the United States.

87. The Takeda Defendants have transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

88. The Takeda Defendants have derived substantial revenue from PPI Products in each of the States and Territories of the United States.

89. The Takeda Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

90. Defendants are each multinational Fortune 500 companies that have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their respective PPI Product(s) in each of the States and Territories of the United States, including in this County.

91. Defendants have significant contacts within this County such that they are subject to the personal jurisdiction of this Court.

FACTUAL ALLEGATIONS

A. General Background: Proton Pump Inhibitors

92. PPI Products are indicated for the treatment of the following conditions: GERD; dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

93. PPI Products work by inhibiting the secretion of stomach acid. They shut down acid production of the active acid pumps in the stomach, thereby reducing hydrochloric acid in

parietal cell to secrete gastric acid.

94. PPI Products are one of the most commercially successful groups of medication in the history of pharmaceutical sales in the United States. Upon information and belief, from 2003 to the present, PPIs have been one of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

95. As of 2009, approximately 21 million Americans used one or more prescription PPI Products, accounting for nearly 20% of the drugs' global sales and earning an estimated \$11 billion annually.

96. Between the period of 2008 and 2013, prescription PPI Products had sales of over \$50 billion with approximately 240 million units dispensed.

97. According to the 2011–2012 National Health and Nutritional Examination Survey, 7.8% of US adults had used prescription PPI Products within the last 30 days.

B. PPI Products Cause Severe Kidney Injuries

98. As early as October 1992, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article reporting PPI usage associated with kidney injury in *The American Journal of Medicine*.

99. Since 1992, there have been numerous adverse case reports and scientific studies published in medical journals and reported by physicians and scientists, as well as adverse reports from national adverse drug registries, which document an association between use of PPI Products and the occurrence of kidney injuries such as AIN, AKI, ARF CKD and ESRD.

i. PPI-Induced Acute Interstitial Nephritis (“AIN”)

100. Since 1992, numerous case reports have been published in the medical literature documenting an association between the use of PPI Products and the development of AIN amongst patients.

101. In 2006, researchers at the Yale School of Medicine conducted a case series published in the International Society of Nephrology's Kidney International finding that PPI Product use, by way of AIN, left most patients "with some level of chronic kidney disease."

102. In 2007, F. Sierra et al. published an article in the Journal of Alimentary Pharmacology and Therapeutics, titled, "Systematic review: proton pump inhibitor-associated acute interstitial nephritis." The researchers concluded that long-term use of proton pump inhibitors is associated with interstitial nephritis.

103. In February 2007, Harmark et al. published their findings in the British Journal of Clinical Pharmacology that AIN could be induced by a variety of available PPI Products and was indicative of a class-effect and that this finding was further supported by adverse event data from the World Health Organization Collaborating Centre for International Drug Monitoring, "where PPI-induced AIN is disproportionately present in the database." Harmark et al., Proton-pump inhibitor-induced acute interstitial nephritis, BJ Clin. Pharm. (2007).

104. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a Citizen's Petition with the FDA seeking the addition of safety information concerning several risks associated with PPI Product usage, including, among others, PPI-induced AIN.

105. According to the Public Citizen petition, at the time of the filing there was "no detailed risk information on any PPI for this adverse effect."

106. On October 31, 2014, more than three years after Public Citizen's petition, the FDA responded by requiring consistent labeling regarding the risk of AIN on all prescription PPI Products.

107. The FDA found that there was "reasonable evidence of a causal association" and therefore, concluded "that the prescription PPI labeling should be consistent with regard to this risk[.]"

108. In December of 2014, all labels for prescription PPI Products were required to include the following information:

Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [PPI] if acute interstitial nephritis develops.

109. To this date, Defendants' over-the-counter PPI Products do not include a warning or any risk information about AIN.

110. The current warning contained on prescription PPI Products regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences. If left untreated, AIN can lead to Chronic Kidney Disease, Renal Failure, Dialysis, Kidney Transplant and/or death.

111. Defendants have also failed to adequately inform physicians, and other healthcare providers such as pharmacists, and consumers regarding the risk of AIN and the use of over-the counter PPI Products.

112. PPI Products and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate AIN, a sudden kidney inflammation that can result in mild to severe problems.

113. PPI-induced AIN can be difficult to diagnose, with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea and weakness.

114. Use of PPI Products may lead to subclinical AIN according to multiple studies, including but not limited to:

- a. Lazarus B, Chen Y, Wilson FP, et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*. 176 JAMA INTERNAL MED. 238 (2016); and

SOC. NEPHROL. 2926 (2016).

115. AIN's slow presentation can cause significant damage over time without those affected exhibiting acute symptoms.

116. Where AIN is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AIN can lead to Chronic Kidney Disease and End Stage Renal Disease requiring the patient to undergo permanent dialysis, kidney transplant or, in some cases, death.

117. While AIN can be treated, once AIN has progressed to CKD it is incurable and can only be managed.

ii. PPI-Induced Acute Kidney Injury ("AKI")

118. Acute Kidney Injury is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly.

119. Studies indicate that those using PPI Products are at a more than 2.5 times greater risk than the general population to suffer AKI.

120. Studies also indicate that those who develop AIN are at a significant risk of AKI, even though they may not obviously exhibit kidney dysfunction.

121. Currently, the product labeling for PPI Products, both prescription and over-the-counter, does not contain any warning regarding the increased risk of AKI.

122. Where AKI is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AKI can lead to CKD and ESRD.

iii. PPI-Induced Chronic Kidney Disease ("CKD")

123. Chronic Kidney Disease is the gradual loss of kidney function. Kidneys filter Waste and excess fluid from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and waste can build up in the body.

124. CKD can ultimately progress to End Stage Renal Disease in which total kidney function is lost and patients must either undergo dialysis or have a kidney transplant to survive.

125. In January 2016, a study published in the Journal of the American Medical Association found that use of PPI Products was independently associated with a 20 – 50% higher risk of CKD.

126. In February 2016, a study published in the Journal of the American Society of Nephrology found that “exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of ESRD.”

127. In April 2016, a study published in the Journal of Nephrology suggested that the development of and failure to treat AIN could lead to CKD and ESRD, which requires dialysis or kidney transplant to manage. Analyses of the study were adjusted for age, sex, race, baseline eGFR, cigarette smoking, BMI, systolic blood pressure, diabetes, a history of cardiovascular disease, antihypertensive medication use, anticoagulant medication use, statin, aspirin and NSAID use. Across all groups, “each of these sensitivity analyses showed a consistent association between PPI use and a higher risk of CKD.”

128. CKD is often a slow progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

129. PPI Products have also been shown to cause CKD independent of, and in the absence of, an intervening AKI or AIN event, even where the AKI or AIN is subclinical. For example, the results of a 2017 epidemiologic study “showed a significant association between PPI use and chronic renal outcomes including incident CKD, CKD progression, and ESRD in the absence of intervening AKI.” Yan Xie et al., Long-Term Kidney Outcomes among Users of Proton Pump Inhibitors without Intervening Acute Kidney Injury, 91 Kidney Int’l 1482 (2017).

information about CKD.

C. PPI Products Cause Rebound Acid Hypersensitivity, Worsening GERD and Acid Reflux, Creating Dependency

131. Users of PPI Products will, and have, experienced worse GERD, or acid reflux, upon ceasing PPI Product use, evidencing that PPI Products can lead to physical dependency and/or the worsening of symptoms upon removal of the PPI therapy.

132. The worsening of GERD or acid reflux after withdrawal of PPI Products has been characterized by scientists as “rebound acid hypersecretion” and is characterized by an increase in acid secretion with the withdrawal of the PPI Products.

133. This phenomenon was first identified during preclinical animal studies on rats treated with omeprazole/Prilosec.

134. Because PPI Products work by preventing the acidification of the stomach’s contents by blocking the proton pumps of the stomach, the body may react by compensating with increased production of gastrin, a hormone that stimulates secretion of gastric acid. Consequently, when users discontinue treatment with PPI Products, their bodies’ acid production increases beyond their pre-PPI treatment levels.

135. The increase in acid production after discontinuation of PPI Products caused and will continue to cause Plaintiff significant harm and a dependency on PPI Products.

136. After Plaintiff’s discontinuation of PPI Products, increased acid production to a level above that which existed before treatment with PPI Products was initiated has caused and will cause Plaintiff to treat GERD as a more severe condition than that which existed when PPI Products were initiated.

137. Several studies have shown that treatment with PPI Products induces acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment is withdrawn in healthy individuals who have never before experienced heartburn or related symptoms.

138. Due to Rebound hypersecretion, patients are unable, in many instances, to cease use of PPI Products, despite choosing and wanting to do so after learning of the risks of using PPI Products, including kidney injuries.

139. To date, the labeling for the Defendants' respective PPI Products contains no information regarding rebound acid hypersecretion or information that would assist healthcare providers and/or patients who suffer from this after ceasing to use PPI Products.

D. Safer Alternatives to PPIs

140. Despite the fact that PPI Products lead to an increased risk of such severe injuries as outlined herein, several safer alternatives have been and are available, including but not limited to:

- a. The use of over-the-counter calcium carbonate tablets that have been available since the 1930s, such as Maalox and Tums; and/or
- b. The use of histamine H₂-receptor antagonists (also known as "H₂ Blockers") that were developed in the late 1960s. H₂ Blockers act to prevent the production of stomach acid, work more quickly than PPI Products and are prescribed for the same indications as PPI Products. Examples of H₂ Blockers include Zantac, Pepcid and Tagamet. H₂ Blockers are not associated with an increased risk of kidney injuries.

141. In spite of their commercial success and global popularity, up to 70% of PPI Products may be used inappropriately for indications or durations that were never tested or approved. D. Marks, *Time to Halt the Overprescribing of Proton Pump Inhibitors*, THE PHARMACEUTICAL JOURNAL (Aug. 8, 2016).

142. Consumers, including Plaintiff, who have used Defendants' PPI Products for the treatment of increased gastric acid have and had several alternative safer treatments available and have not been adequately warned about the significant risks and lack of benefits associated with use of PPI Products.

E. Injuries Resulting from PPI Products

143. The use of PPI Products for time periods longer than those tested or approved is a direct consequence of Defendants' (1) failure to adequately and specifically warn patients and healthcare providers as to the appropriate length of usage; (2) failure to provide adequate, clear and accurate marketing materials regarding appropriate usage of PPI Products and the appropriate and approved indications; and (3) engaging in off-label promotion of their respective PPI Products for indications that were not approved, and upon which Plaintiff and their respective prescribing physicians relied upon when making prescribing decisions.

144. As a result of the defective nature of Defendants' PPI Products, persons who ingested Defendants' PPI Products have been exposed to significant risks stemming from unindicated and/or long-term usage, even when used as directed and/or prescribed by a physician or healthcare professional.

145. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from severe kidney injuries including, but not limited to, AIN, AKI, CKD and ESRD.

146. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from a worsening of acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment with Defendants' PPI Products was withdrawn and have developed and suffered from a physical dependence on PPI treatment.

F. Defendants' Actively Concealed the Dangers Associated with Use of PPI Products

147. Defendants, through their affirmative misrepresentations and/or omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with the use of Defendants' PPI Products.

148. Defendants concealed and continue to conceal from Plaintiff, other consumers and/or the medical community that Defendants' PPI Products can cause kidney injuries. Specifically, Defendants failed to adequately inform Plaintiff, other consumers and/or the medical community about the serious risks associated with Defendants' PPI Products, and

still fail to warn of these risks, even to this day. Defendants have concealed and continue to conceal and have failed to adequately inform Plaintiff, other consumers, Plaintiff's physicians and/or others within the medical community that over-the-counter PPI Products are associated with AIN, and fail to warn and inform regarding the risk of AIN developing into CKD and ESRD.

149. Defendants concealed and continue to conceal that Defendants' PPI Products can cause consumers to become physically dependent on PPI treatment. Specifically, Defendants have failed to inform consumers and/or healthcare providers that a patient's symptoms may worsen after the withdrawal of PPI Products.

150. As a result of Defendants' actions, Plaintiff and/or Plaintiff healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Master Long Form Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations.

151. Plaintiff would not have used Defendants' PPI Products had Defendants properly disclosed the risks associated with long-term use.

152. Defendants had an obligation to comply with the law in the manufacture, design and sale of Defendants' respective PPI Products.

153. Materials, including advertisements, press releases, website publications and other communications regarding Defendants' PPI Products, are part of the labeling of the Defendants' respective PPI Products, and Defendants could have altered the same without FDA approval.

154. Defendants' marketing campaigns willfully and intentionally misrepresented the risks of PPI Products and failed to warn about the risks of acute interstitial nephritis, acute kidney failure, chronic kidney disease and other kidney injuries.

indications that were not approved, including, but not limited to, long-term ingestion of PPI Products for a duration for which the products were not originally approved.

155. Defendants engaged in off-label promotion of their respective PPI Products for

156. Defendants' marketing campaigns and advertising to consumers failed to adequately instruct consumers regarding the appropriate duration for using their respective over-the-counter PPI Products.

157. Defendants knew or should have known of the risks of AIN, AKI, CKD and ESRD based on the data available to them or that could have been generated by them, including, but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, preclinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

158. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AIN.

159. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AKI.

160. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of CKD.

161. At all times, Defendants could have implemented changes to the labeling of their respective PPI Products regarding the risks of AIN, AKI, CKD and ESRD.

G. Defendants Violations of Federal Law

162. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

163. With respect to Defendants' PPI Products, Defendants have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. § 352 because, among other things, their labeling is false or misleading;

b. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. § 352 because words, statements or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

c. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. § 352 because their labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;

d. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. § 352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof;

e. Defendants' PPI Products do not contain adequate directions for use pursuant to 21 CFR § 201.5, because of, among other reasons, omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application;

prescription PPI Products were and are not informative and accurate;

g. Defendants' prescription PPI Products are misbranded pursuant to 21 CFR § 201.56 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading;

h. Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for monitoring of patients who took their respective prescription PPI Products;

i. Defendants' prescription PPI products are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;

j. Defendants' over-the-counter PPI Products are mislabeled pursuant to 21 CFR §201.66 because they were and are not informative and accurate;

k. Defendants' over-the-counter PPI Products are misbranded pursuant to 21 CFR §201.66 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false or misleading;

l. Defendants' PPI Products violate 21 CFR § 210.1 because the process by which they were manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meet the quality and purity characteristic that they purport or are represented to possess;

m. Defendants' PPI Products violate 21 CFR § 210.22 because the labeling and packaging materials do not meet the appropriate specifications;

Defendants employed are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented;

o. Defendants' PPI Products violate 21 CFR § 211.165 in that they fail to meet established standards or specifications and any other relevant quality control criteria;

p. Defendants' PPI Products violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the PPI Products were not followed;

q. Defendants' PPI Products violate 21 CFR § 310.303 in that they are not safe and effective for their intended use;

r. Defendants violated 21 CFR § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA;

s. Defendants violated 21 CFR § 310.305 and 314.80 by failing to report adverse events associated with their respective PPI Products as soon as possible or at least within 15 days of the initial receipt of the adverse drug experience report;

t. Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with their respective PPI Products, and evaluating the cause of the adverse event;

u. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA;

of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences;

v. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports it submitted properly, such as by labeling them as “15-day Alert report,” or “15-day Alert report follow-up”;

x. Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of Defendant’s PPI Products or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor;

y. Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated); and

z. Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

aa. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff.

APPLICABLE STATUTES OF LIMITATIONS

164. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

165. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including but not limited to equitable tolling, class action tolling, delayed discovery, discovery rule and fraudulent concealment.

166. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until the Plaintiff knew or, through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

167. Despite diligent investigation by the Plaintiff into the cause of their injuries, the nature of the Plaintiff's injuries and damages and their relationship to the PPI Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

168. The running of the statute of limitations in this case is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and/or the consuming public of the true risks associated with the PPI Products. As a result of the Defendants' fraudulent concealment, the Plaintiff and/or Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence, that the

proximate result of the wrongful acts and omissions of the Defendants.

169. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPI Products. The Defendants were under a duty to disclose the true character, quality and nature of PPI Products because this was nonpublic information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, their medical providers and/or to their health facilities.

170. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and/or medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks and, instead, were forced to rely on Defendants' representations.

171. Defendants were and continue to be in possession of information and data that shows the risk and dangers of these products that is not otherwise in the possession or available to Plaintiff and/or their healthcare providers.

172. At the time of the Plaintiff's injuries, Plaintiff and/or the Plaintiff's healthcare providers were not aware of any facts which would have made a reasonably prudent person suspicious of Defendants' wrongdoing because the Plaintiff and the Plaintiff's healthcare providers reasonably relied on Defendants' representations that PPI Products do not cause kidney injury and/or death.

173. At no time prior to the Plaintiff's eventual discovery of wrongdoing did any of Plaintiff's doctors ever inform, advise, suggest or otherwise imply that the Plaintiff's PPI Product use was a potential contributing cause of the Plaintiff's kidney injuries.

174. Plaintiff reasonably relied on the skill and judgment of the Plaintiff's doctors and had no reason to further investigate, inquire into or suspect that PPI Products caused the Plaintiff's conditions.

175. Plaintiff exercised reasonable diligence in an attempt to discover the cause of their kidney injuries. Plaintiff relied on their physicians to advise them of any known complications. Plaintiff had no reason to believe their injuries were the result of any wrongdoing, whether intentional and/or negligent, until the discovery dates suggested below and are therefore relying on the benefit of the discovery rule.

176. The Plaintiff had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at the time of his injury.

177. At the time of Plaintiff's injuries, Plaintiff did not have access to or actually receive any studies or information recognizing the increased risk of kidney injuries with PPI Product use or have any discussions with their doctors that there was an association between their kidney injuries and PPI Product use.

CAUSES OF ACTION

COUNT I **STRICT PRODUCT LIABILITY**

178. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

179. At the time of Plaintiff's injuries, the PPI Products manufactured by the Defendants were defective and unreasonably dangerous to foreseeable consumers, including Plaintiff.

180. At the time of the Plaintiff's injuries, Defendants placed PPI Products into the stream of commerce that were defective and in an unreasonably dangerous condition to foreseeable users, including the Plaintiff.

181. At all times herein mentioned, Defendants have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed PPI Products as described herein that were used by the Plaintiff.

182. Defendants' PPI Products were expected to and did reach consumers, handlers and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by the Defendants.

183. Defendants' PPI Products were manufactured in an unsafe, defective and inherently dangerous condition, which was dangerous to users, including the Plaintiff.

184. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the PPI Products.

185. At all times herein mentioned, the PPI Products were in a defective condition and unsafe, and Defendants knew or had reason to know that their PPI Products were defective and unsafe, including when used in the formulation and manner recommended by the Defendants.

186. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants, manufacturers and/or suppliers, the PPI Products were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect, and more dangerous than other medications on the market designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

187. Defendants knew or should have known that at all times herein mentioned their PPI Products were in a defective condition and were and are inherently dangerous and unsafe.

188. At the time, the Plaintiff used Defendants' PPI Products, the PPI Products were being used for the purposes and in a manner normally intended and foreseeable, namely to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

189. Defendants, with this knowledge, voluntarily designed their PPI Products in a dangerous condition for use by the public and the Plaintiff.

190. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended and foreseeable use.

191. Defendants created a product unreasonably dangerous for its intended and foreseeable use.

192. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that PPI Products left the hands of Defendants in a defective condition and were unreasonably dangerous to its intended users.

193. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which they were manufactured.

194. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

195. Plaintiff could not, by the exercise of reasonable care, have discovered the PPI Products' defects herein mentioned and perceived their danger.

196. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including kidney injuries and other severe and personal injuries which are permanent and lasting in nature, and the Defendants failed to adequately warn of said risk.

197. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including rebound acid hypersecretion, and the Defendants failed to adequately warn of said risk.

198. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products were ineffective for their intended use of treating peptic disorders, including GERD, peptic ulcer disease, and non-steroidal anti-inflammatory drug induced gastropathy, and that there were less dangerous alternatives on the market to treat peptic disorders.

199. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

200. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate postmarketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks and severe and permanent health consequences from ingesting PPI Products, they failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote their PPI Products.

201. The PPI Products ingested by the Plaintiff were in the same or substantially similar condition as they were when they left the possession of Defendants.

202. Plaintiff did not misuse or materially alter the PPI Products.

203. Defendants are strictly liable for the Plaintiff's injuries in the following ways:

- a. The PPI Products as designed, manufactured, sold and supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
- b. Defendants failed to properly market, design, manufacture, distribute, supply and sell their PPI Products;
- c. Defendants failed to warn and place adequate warnings and instructions on their PPI Products;
- d. Defendants failed to adequately test their PPI Products;
- e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of PPI Products; and
- f. Feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating the Plaintiff's conditions, while decreasing the risk of kidney injuries.

204. By reason of the foregoing, Defendants are strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective PPI Products.

205. Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

206. These defects in Defendants' PPI Products were a substantial factor in causing the Plaintiff's injuries.

207. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

208. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including the Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, the Plaintiff, and/or the Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, the Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II

STRICT PRODUCT LIABILITY –DESIGN DEFECT

209. Plaintiff incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. The Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

210. At all times relevant, Defendants' PPI Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce.

211. Defendants' PPI Products were defective in design or formulation in that they were not merchantable, reasonably suitable and/or safe for their intended and foreseeable use,

sustained by Plaintiff.

212. Defendants' PPI Products did not perform safely or as Plaintiff or an ordinary consumer would have expected.

213. At all times relevant, the PPI Products were used as intended or in a way reasonably foreseeable to the Defendants.

214. Defendants placed their PPI Products into the stream of commerce with wanton and reckless disregard for public safety.

215. At all times relevant, Defendants' PPI Products were expected to reach, and did reach, Plaintiff, without substantial change in the condition in which they were sold.

216. The PPI Products were sold in an unsafe, defective and inherently dangerous Condition.

217. The PPI Products contained defects in their design which render the drugs dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants. The design defects render the PPI Products more dangerous than other drugs designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy, and cause an unreasonable increased risk of injury, including but not limited to life-threatening kidney injuries.

218. The PPI Products were in a defective condition and unsafe, and Defendants knew, had reason to know or should have known that the PPI Products were defective and unsafe, even when used as instructed.

219. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of serious kidney injuries that may be irreversible, permanently disabling and life-threatening, is high in light of the intended and reasonably foreseeable use of the PPI Products.

higher than necessary.

221. It is unlikely that users would be aware of the risks associated with Defendants' PPI Products, and Plaintiff specifically were not aware of these risks, nor would they expect such risks.

222. The PPI Products manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of PPI Products, as defined by Ohio Rev. Code §§ 2307.75(B) exceeded the benefits associated with the design or formulation of the PPI Products, as defined by Ohio Rev. Code. §§ 2307.75(C), or they were more dangerous than an ordinary consumer would expect.

223. As set forth elsewhere in this Complaint, the foreseeable risks of the PPI Products, as defined at Ohio Rev. Code. §§ 2307.75(B)(1)-(5), include but are not limited to the following:

- a. the nature and magnitude of risks associated with the product design in light of the intended and reasonably foreseeable uses, as defined at Ohio Rev. Code §§ 2307.75(B)(1);
- b. the unlikely awareness to the users of PPI Products of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of PPI Products, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(2);
- c. the high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use as PPI Products, among other reasons, as defined at Ohio Rev. Code §§ 2307.75(B)(3);
- d. the design or formulation of PPI Products produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there were available, more effective

and other available treatments, existed that were capable of treating Plaintiff's conditions, while not as prone to cause injury, as defined at Ohio Rev. Code §§ 2307.75(B)(4), specifically, the risk of kidney injuries.

- e. the design or formulation of PPI Products produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using PPI Products, all as defined at Ohio Rev. Code §§ 2307.75(B)(5).

224. The design of Defendants' PPI Products did not conform to any applicable public or private product standard that was in effect when the PPI Products left the Defendants' control.

225. The PPI Products' designs are more dangerous than a reasonably prudent consumer would expect when used in their intended or reasonably foreseeable manner. The PPI Products are more dangerous than Plaintiff expected.

226. The intended or actual utility of PPI Products is not of such benefit to justify the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

227. At the time the PPI Products left Defendants' control, it was both technically and economically feasible to have an alternative design that would not have caused kidney injuries that may be irreversible, permanently disabling and life-threatening, or an alternative design that would have substantially reduced the risk of these injuries.

228. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

229. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from Plaintiff, the medical community and the general public. Defendants made conscious decisions not to warn or inform the

damages.

230. The unreasonably dangerous nature of Defendants' PPI Products caused serious harm to Plaintiff.

231. Defendants' PPI Products are defective in their design which renders the PPI Products dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants.

232. The design defects render the PPI Products more dangerous than other products used for the same intended purpose, and cause an unreasonable increased risk of harm.

233. The PPI Products' design is defective and unsafe, and Defendants knew or had reason to know that the PPI Products were defective and unsafe in their design when used as instructed and in a foreseeable manner for the treatment of peptic disorders by consumers, including the Plaintiff.

234. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of kidney injury that may lead to permanently disabling and life threatening or life-ending conditions, was high in light of the intended and reasonably foreseeable use of PPI Products by patients for treatment of peptic disorders.

235. Users of PPI Products would not be aware of the risks of kidney injuries associated with either the defective design or warnings associated with PPI Products through warnings, general knowledge or otherwise, and Plaintiff was specifically unaware of these risks, and would not be expected to be aware of these risks.

236. The intended or actual utility and benefit of the PPI Products does not justify the risk of kidney injuries that may be irreversible, permanently disabling, life-threatening or life-ending.

237. The design of the PPI Products was negligently formulated by the Defendants in disregard of the known risk of kidney injury.

negligently formulated by the Defendants in disregard of the known risk of kidney injury.

239. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of rebound acid hypersecretion.

240. The defects in design and warnings caused and/or increased the risk of harm of Plaintiff's injuries and damages.

241. The Defendants failed to provide an adequate warning as to the risks of PPI Products and for this reason Defendants may not claim that PPI Products are not defective in design or formulation, though it is unsafe, as contemplated under Ohio Rev. Code §§ 2307.75(D).

242. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

243. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

244. Additionally, as a direct and proximate result of the foregoing, Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

245. The defective nature of the PPI Products was a substantial factor in causing Plaintiff's injuries.

246. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

247. Defendants' conduct, as described herein, was extreme and outrageous.

248. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

249. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

250. Defendants manufactured, distributed and/or sold the PPI Products that were dangerous and presented a high risk of serious kidney and related personal injuries when used as intended or in foreseeable way, notwithstanding the Defendants' knowledge of an increased

of such risks, as defined at Ohio Rev. Code §§ 2307.76(A)(1)(a) – (b).

251. In addition to, or in the alternative, the PPI Products manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instructions since, after Defendants knew or should have known of the risk of serious bodily harm as a result of PPI Products, Defendants failed to provide an adequate warning to consumers and/or their healthcare providers of the product, knowing the product could cause serious injury, as defined at Ohio Rev. Code §§ 2307.76(A)(2)(a) – (b).

252. Defendants had a duty to warn Plaintiff and their healthcare providers regarding the risks associated with ingesting PPI Products and failed to warn of the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening.

253. Defendants knew, or in the exercise of reasonable care should have known, about the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening that are associated with use of their PPI Products.

254. Defendants failed to provide adequate warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of kidney injury that may be irreversible, permanently disabling and life-threatening in light of the likelihood that the PPI Products would cause these injuries.

255. The risks of PPI Products were not open and obvious, as defined at Ohio Rev. Code Code §§ 2307.76(B).

256. Defendants failed to update warnings based on information received from surveillance and research conducted after their PPI Products were first approved by the FDA and marketed, sold and used in the United States and throughout the world.

257. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using PPI Products after FDA approval.

258. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

259. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of rebound acid hypersecretion that would assist healthcare providers and/or patients who suffer from this after ceasing use of PPI Products.

260. Plaintiff used the PPI Products for their approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

261. Plaintiff and/or Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived the danger of PPI Products because the risks were not open or obvious.

262. Defendants, as the manufacturers and distributors of the PPI Products, are held to the level of knowledge of an expert in the field.

263. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

264. The warnings that were given by the Defendants failed to properly warn Plaintiff and/or Plaintiff's healthcare providers of the risks associated with the PPI Products, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and/or Plaintiff through their healthcare providers, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

265. Defendants had a continuing duty to warn Plaintiff and/or Plaintiff's healthcare providers of the dangers associated with their PPI Products.

266. Had Plaintiff and/or his healthcare providers received adequate warnings regarding the risks associated with the use of PPI Products, they would not have used them or they would have altered the frequency or duration of use.

267. Defendants failed to update warnings based on information received after the PPI Products entered the market, and continued to market, promote, detail, distribute and sell PPI Products without appropriately updated and amended warnings.

268. A manufacturer exercising reasonable and prudent care would have updated warnings on the PPI Products on the basis of epidemiology studies and/or reports of injuries to individuals using PPI Products after FDA approval.

269. Plaintiff and his healthcare providers were led to believe, through Defendants' use of aggressive and pervasive marketing, promotion and detailing, that Defendants' PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

270. The warnings and instructions that were given by Defendants to healthcare providers were not accurate or clear, and were, in fact, false and misleading.

271. The warnings that were given by the Defendants failed to properly warn physicians and/or other healthcare providers, including those of the Plaintiff, of the risks associated with Defendants' PPI Products, thereby subjecting patients, including the Plaintiff, to unreasonable and foreseeable risks that exceeded the purported and marketed benefits of Defendants' PPI Products.

272. Plaintiff's healthcare providers reasonably relied upon the representations, warning and instructions provided by Defendants for use and administration of their PPI Products.

273. Had the Plaintiff and/or their healthcare providers received adequate, appropriate and correct warnings regarding the risks associated with the use of Defendants' PPI Products, these healthcare providers would not have prescribed, recommended, continued to prescribe or continued the recommendation of the PPI Products, or would have altered the duration and frequency of use.

274. Defendants' conduct as described herein was a substantial factor in causing Plaintiff's injuries.

275. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

276. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

277. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

278. Additionally, Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
NEGLIGENCE

279. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

280. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling and/or distributing their PPI Products into the stream of commerce, including a duty to assure that the PPI Products would not cause users to suffer unreasonable, dangerous side effects.

281. Defendants failed to exercise ordinary care in the design, research, manufacture, labeling, warnings, marketing, promotion, quality assurance, quality control, sale and/or distribution of their PPI Products in that Defendants knew or should have known that the drugs could proximately cause Plaintiff's injuries and/or presented an unreasonably high risk of injury.

282. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their PPI Products, including but not limited to the following particular respects:

- a. Failing to use due care in design and/or manufacture of the PPI Products so as to avoid the aforementioned risks to individuals;
- b. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their PPI Products;

- c. Failing to use reasonable and prudent care so as to conduct sufficient postmarketing pharmacovigilance and pharmacosurveillance;
- d. Failing to recognize the significance of their own and other testing, and information regarding PPI Products, which testing and information evidenced such products are dangerous and potentially harmful to humans;
- e. Failing to respond promptly and appropriately to their own and other testing, and information regarding PPI Products, and failing to promptly and adequately warn of the potential for kidney injuries including acute interstitial nephritis, acute kidney injuries and chronic kidney disease, when using their PPI Products;
- f. Failing to promptly, adequately and appropriately recommend testing and monitoring of patients upon whom PPI Products were used in light of the PPI Products' dangers and potential harm to humans;
- g. Failing to properly, appropriately and adequately monitor the post-market performance of their PPI Products and such products effects on patients;
- h. Aggressively promoting, marketing, advertising and/or selling their PPI Products given their knowledge and experience of their PPI Products' potential harmful effects;
- i. Failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of using their PPI Products, which were knowingly false and misleading, in order to influence patients, such as the Plaintiff, to use their PPI Products in excess and/or in preference to safer and effective alternative treatments;
- j. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of kidney injury associated with the use of their PPI Products;

- regarding all possible adverse side effects and risk of rebound acid hypersecretion associated with the use of their PPI Products;
- l. Failing to disclose to Plaintiff and/or the medical community their full knowledge and experience regarding the potential dangers and harm associated with use of their PPI Products;
 - m. Failing to disclose to Plaintiff and/or the medical community in an appropriate and timely manner, facts relative to the potential dangers and harm associated with use of their PPI Products;
 - n. Failing to warn Plaintiff and/or Plaintiff's healthcare providers of the severity and duration of such adverse effects;
 - o. Failing to warn Plaintiff and/or Plaintiff's healthcare providers prior to actively encouraging the sale of their PPI Products, either directly or indirectly, orally or in writing, about the increased risk of kidney injury;
 - p. Placing and/or permitting the placement of PPI Products into the stream of commerce without adequate warnings that they are harmful to humans and/or without properly warning of said products' dangerousness;
 - q. Failing to withdraw their PPI Products from the market and stream of commerce, or restrict their use and/or warn of such products' potential dangers, given their knowledge of the dangers and harms associated with use of their PPI Products;
 - r. Failing to respond or react promptly and appropriately to reports of their PPI Products causing harm to patients;
 - s. Disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of their PPI Products and their potential harm to humans;

- PPI Products;
- u. Failing to exercise reasonable care in informing physicians and healthcare providers using PPI Products about their own knowledge regarding the potential dangers and harm associate with use of their PPI Products;
 - v. Failing to adequately warn Plaintiff and/or Plaintiff's healthcare providers of the known or reasonably foreseeable danger that Plaintiff would suffer serious injuries or death by ingesting Defendants' PPI Products;
 - w. Promoting PPI Products in advertisements, websites and other modes of communication aimed at creating and/or increasing user and consumer demand without regard to the dangers and risks associated using PPI Products;
 - x. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries associated with their PPI Products;
 - y. Failing to use due care under the circumstances; and
 - z. Other such acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

283. Despite the fact that Defendants knew or should have known that the PPI Products caused unreasonable, dangerous risk of kidney injury, Defendants continued to market the PPI Products to consumers, including the medical community and Plaintiff.

284. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described herein, including the failure to comply with federal requirements.

285. It was foreseeable to Defendants that Defendants' PPI Products, as designed and marketed, would cause serious injury to consumers, including Plaintiff.

286. Despite the fact that Defendants knew or should have known that their PPI Products caused unreasonable risks of harm when used as intended by the Defendants, the Defendants continued to advertise, market and sell their PPI Products to patients, including the Plaintiff and healthcare providers.

287. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

288. Defendants' knowingly and intentionally defectively designed and provided inadequate warnings relating to the design of the PPI Products in willful, wanton and reckless disregard for the safety and well-being of all patients and consumers, including the Plaintiff, for the purpose of achieving profits and market share over safety.

289. Defendants acted in reckless disregard to public safety and well-being, including Plaintiff's safety and well-being, and with actual knowledge that the PPI Products were unsafe for their recommended use for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

290. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, Plaintiff, and/or Plaintiff's healthcare providers concerning the dangers of PPI Products, and consciously decided to aggressively market and sell their PPI Products, putting economic, financial and market share advantage over safety and efficacy considerations.

291. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

292. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff,

knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
NEGLIGENCE PER SE

293. Plaintiff incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

294. Defendants violated the Federal Food, Drug and Cosmetic Act 21 U.S.C. §301, et seq., and regulations as described herein, including but not limited to 21 U.S.C. §352, 21, CFR § 201.5, 21 CFR § 201.56, 21 CFR § 201.57, 21 CFR § 201.66, 21 CFR § 210.1, 21 CFR § 210.122, 21 CFR § 211.165, 21 CFR § 211.198, 21 CFR § 310.303, 21 CFR §310.305, 21 CFR § 314.80, and 21 CFR § 312.32.

295. These statutes and regulations are aimed at preserving the health and safety of Plaintiff and the general public.

296. Defendants' acts were the proximate cause and/or a substantial factor in bringing about the harm to the Plaintiff as alleged herein.

297. Plaintiff is among the class of individuals that these statutes and regulations were designed to protect.

298. Plaintiff's injuries are the type that these federal statutes and regulations were intended to prevent.

299. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

300. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI **NEGLIGENCE – FAILURE TO TEST**

301. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

302. At all times relevant, Defendants had a duty to Plaintiff to test the PPI Products so that they were reasonably safe for their foreseeable use, including a duty to conduct proper safety studies and to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to its consumers and users.

303. Defendants did not perform adequate testing on the PPI Products, which were defectively designed, formulated, tested, manufactured, inspected, distributed, marketed, supplied and/or sold to Plaintiff.

304. Defendants also failed to properly and adequately test the PPI Products to discover their potential for causing deleterious, permanent, and profound injuries to the Plaintiff.

305. Defendants failed to properly and adequately analyze the data resulting from pre-marketing tests of PPI products.

306. Additionally, Defendants failed to conduct adequate and sufficient post-market testing and surveillance of PPI Products.

307. Through the formulating of the PPI Products, and before the initiation of the drugs' mass manufacture, Defendants knew or should have known in the exercise of ordinary care that the chemical reactions inherent to PPI Products' mechanism of action would present a health hazard to potential users such as the Plaintiff named herein.

308. Adequate testing would have revealed the serious injuries, including but not limited to renal injury and/or failure caused by the use of the PPI Products.

309. The dangers presented by the PPI Products are so great that reasonable healthcare professionals would not prescribe their use if they knew of the risks.

310. Defendants knew or reasonably should have known that Plaintiff would foreseeably suffer economic damages and/or injuries and/or be at an increased risk of suffering damages and injuries as a result of their failure to exercise ordinary care in the design of the PPI Products by failing to conduct appropriate testing.

311. Defendants are strictly liable for the Plaintiff's injuries resulting from the Defendants' failure to test their PPI Products.

312. As a direct and proximate result of Defendants' wrongful actions and failure to test, the Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries and economic damages incurred through the treatment for the renal failure and renal injuries caused by PPI Product use.

treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII
STRICT PRODUCTS LIABILITY DUE TO NON CONFORMANCE WITH
REPRESENTATIONS PURSUANT TO R.C. 2307.77

313. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

314. Defendants are the manufacturers, designers, distributors, sellers and/or suppliers of PPI Products and made representations regarding the character or quality of PPI Products including but not limited to the fact that PPI Products were safe and effective in its ordinary use.

315. The PPI Products manufactured and supplied by Defendants were defective in that, when it left the hands of Defendants, they did not conform to representations made by Defendants concerning the product, as defined at Ohio Rev. Code §§ 2307.77.

316. These material misrepresentations made by the Defendants were false.

317. Plaintiff justifiably relied upon Defendants' representations regarding PPI Products.

318. Upon information and belief, the warnings provided to those who chose to use the PPI Products, including the Plaintiff were not adequate, as defined at Ohio Rev. Code §§ 2307.76(C).

319. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by

such harm, as set forth in the Ohio Revised Code, including but not limited to Ohio Rev. Code § 2307.73(A).

320. As a direct and proximate result of the foregoing, Plaintiff are entitled to damages pursuant to the Ohio Rev. Code §§ 2307.71-.80, including but not necessarily limited to Ohio Rev. Code §§ 2307.72(A). Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages under the common law and/or Ohio Rev. Code §§ 2307.71-.80, as set forth at Ohio Rev. Code §§ 2307.72(B).

321. Further, as a direct and proximate result of Defendants' wrongful actions and failure to test, Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries; and economic damages incurred through the treatment for the renal failure and renal injuries caused by PPI Product use.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII
BREACH OF EXPRESS WARRANTY

322. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

323. Defendants expressly warranted that their PPI Products were safe and effective to members of the consuming public, including Plaintiff.

324. Defendants expressly warranted that their PPI Products were safe and effective products for use by members of the consuming public, including the Plaintiff, for the treatment of peptic disorders and did not disclose the material risks that their PPI Products could cause serious kidney injury that may be irreversible, permanently disabling and life-threatening. The representations were not justified by the performance of the PPI Products.

325. Defendants expressly warranted that their PPI Products were safe and effective to use.

326. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers and/or the FDA that their PPI Products were safe and fit for use for the intended purpose, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects they did produce were accurately reflected in the warnings, and that they were adequately tested and fit for their intended use.

327. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that their PPI Products were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

328. Plaintiff and/or their healthcare providers reasonably relied on Defendants' express representations.

329. Defendants' PPI Products do not conform to these express representations because they are not safe and have serious side effects, including kidney injuries and in some cases, death.

330. Defendants breached their express warranty in one or more of the following ways:

a. PPI Products, as designed, manufactured, sold and/or supplied by the

Defendants, were defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

- b. Defendants failed to warn and/or place adequate warnings and instructions on their PPI Products;
- c. Defendants failed to adequately test their PPI Products; and,
- d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from PPI Products.

331. Defendants made statements, affirmations and representations of fact concerning their PPI Products through their advertisements, educational campaigns and multi-platform marketing and promotional initiatives directed at consumers, patients and healthcare providers promoting unnecessary and dangerous use and overuse of their PPI Products.

332. Defendants' statements, affirmations and representations of fact did reach the Plaintiff, and formed a "basis of the bargain" for the Plaintiff's decision to purchase or accept the prescription of PPI Products.

333. Defendants did not disclose material risk of kidney injuries alleged herein that PPI Products caused.

334. Defendants' representations concerning the safety and efficacy of their PPI Products were not justified by their performance or benefits.

335. Defendants expressly warranted that PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. In fact, Defendants, through their advertisements, promoted use of PPI Products for ongoing and daily use. Their PPI Products did not conform to Defendants' representations, statements and/or affirmations of fact in terms of the express warranties made to consumers and patients concerning the drugs' safety and efficacy as formulated for use.

336. Plaintiff reasonably and justifiably relied upon Defendants' representations, statements and/or affirmations of fact that their PPI Products were safe and effective when the Plaintiff chose to purchase, use and continue to use them.

337. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including Defendants' PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and express warranty of the Defendants in the choosing to use Defendants' PPI Products.

338. Defendants herein breached the aforesaid express warranties as their PPI Products were defective.

339. Plaintiff's injuries were the direct and proximate result of Defendants' breach of their express warranty.

340. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

341. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IX
BREACH OF IMPLIED WARRANTY

though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

343. At the time Defendants marketed, distributed and sold their PPI Products to Plaintiff, Defendants warranted that they were merchantable and fit for the ordinary purposes for which it was intended.

344. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

345. The PPI Products were not merchantable and fit for their ordinary purpose, because they have a propensity to lead to the serious personal injuries described in this Complaint.

346. Plaintiff reasonably relied on Defendants' representations that the PPI Products were safe and free of defects and were a safe means of managing and treating symptoms associated with peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

347. At all relevant times hereto, Defendants knew or had reason to know of the purpose for and manner in which users of PPI Products, including Plaintiff, were using the PPI Products, and those users were relying on Defendants' promotional and advertising materials in their selection of the product for that particular use.

348. Through aggressive healthcare provider promotion and patient advertising, educational, informational and marketing campaigns, Defendants participated in the selection of their PPI Products by healthcare providers, patients and consumers.

349. At all relevant times hereto, Defendants' PPI Products did not have the requisite clinical safety or efficacy profiles to be deemed fit for the particular purpose of treating peptic

induced gastropathy.

350. Defendants' PPI Products did not conform to this implied warranty of fitness for the use in treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

351. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and warranty of the Defendants in the choice to use Defendants' PPI Products.

352. The PPI Products were neither safe nor fit for their intended use nor of merchantable quality, as warranted by Defendants to the Plaintiff, in that PPI Products pose a dangerous risk when used as intended to cause serious kidney injuries.

353. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff's injuries.

354. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

355. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT X
NEGLIGENT MISREPRESENTATION

356. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

357. From the time Defendants' PPI Products were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that PPI Products were safe and effective for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale, use and overuse of their PPI Products and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of PPI Products.

358. Defendants had a duty to ensure that the representations they made about their PPI Products were true and complete when made. Defendants made the foregoing representation without any reasonable ground for believing them to be true.

359. At all relevant times hereto, Defendants conducted sales and marketing campaigns to promote the sale of their PPI Products and deceived patients, consumers, physicians and healthcare providers, including the Plaintiff and his healthcare providers, as to the health risks and consequences of the use of their PPI Products.

360. The Defendants made these false and misleading representations without any reasonable ground for believing them to be true concerning the safety and efficacy of PPI Products for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

361. These representations were made directly by Defendants, their sales representatives and other authorized agents of the Defendants to physicians and other healthcare providers; in television media directed towards the general public; in publications, the popular press, and other written materials which were directed to physicians, patients, consumers and the general public; and on Internet websites and applications directed to consumers and physicians, including the Plaintiff, with the intention of inducing and influencing the demands for, as well as the ultimate prescription, purchase and use of their PPI Products.

362. The representations by the Defendants were in fact false, in that their PPI Products are not safe, fit and/or effective for human consumption as labeled, using PPIs Products is hazardous to consumers' health, and PPI Products have a serious propensity to cause serious injuries to users, including but not limited to the kidney and related personal injuries suffered by Plaintiff.

363. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of PPI Products.

364. In reliance on the misrepresentations by the Defendants, Plaintiff was induced to purchase and use PPI Products. If Plaintiff had known the truth and the facts concealed by the Defendants, Plaintiff would not have used the PPI Products or would have used far fewer PPI Products. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know all of the facts.

365. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and

diminished enjoyment of life and financial expenses for hospitalization and medical care.

366. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XI **FRAUD AND FRAUDULENT MISREPRESENTATION**

367. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

368. Defendants fraudulently represented to the medical and healthcare community, patients, consumers and the general public, including the Plaintiff, that their PPI Products had been adequately tested, were safe for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and were accompanied by adequate warnings.

369. Defendants widely advertised, marketed and promoted their PPI Products as safe and effective medications for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and widely advertised, marketed and promoted PPIs as a safe for daily and extended use.

370. These representations were made by the Defendants with the intent of deceiving the medical and healthcare community, patients, consumers, the general public and the Plaintiff, with the intent of inducing the prescription and use of their PPI Products in circumstances that the Defendants knew were dangerous, unsafe and created a high risk of harm.

371. These representations made by Defendants were false and misleading.

372. Defendants knew these representations to be false when made and willfully, wantonly and recklessly disregarded whether the representations were true.

373. Defendants' conduct evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

374. At the time the Defendants made aforesaid representations, Plaintiff used Defendants' PPI Products and was unaware of the falsity of the representations and reasonably believed them to be true.

375. In reliance on Defendants' misrepresentations, Plaintiff was induced to and did use Defendants' PPI Products, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

376. Defendants knew or should have known that their PPI Products had not been sufficiently tested, were defective in nature and/or lacked adequate and/or sufficient warnings.

377. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

378. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

379. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XII

GROSS NEGLIGENCE

380. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

381. The wrong done by the Defendants was aggravated by the kind of malice, fraud, reckless disregard for the rights of others, the public and the Plaintiff and conduct for which the law allows the imposition of exemplary damages, in that the Defendants' conduct:

- a. when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or
- b. Defendants made a material representation that was false, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the

representation and suffered injury as a result of this reliance.

382. Plaintiff, therefore, seeks exemplary damages in an amount within the jurisdictional limits of the court. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence which proximately caused the injuries to Plaintiff. In that regard, Plaintiff seeks exemplary damages in an amount which would punish such Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XIII **FRAUDULENT CONCEALMENT**

383. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

384. Prior to Plaintiff's use of Defendants' PPI Products and, during the period in which Plaintiff actually used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of their PPI Products, including information regarding adverse events, pre and post marketing injuries, and epidemiological studies indicating unreasonable risks associated with using PPI Products.

385. Furthermore, Defendants fraudulently concealed the safety information about the use of their PPI Products. As described herein, Defendants' PPI Products present high risk of kidney injuries not present in other methods and drugs for the treatment of peptic disorders.

386. These representations and omissions were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase their PPI Products, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

387. At the time the aforesaid representations and omissions were made by the Defendants, and at the time the Plaintiff used Defendants' PPI Products, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

388. Defendants fraudulently concealed the safety issues associated with PPI use to induce Plaintiff to purchase and use, and physicians to prescribe and/or recommend their PPI Products.

389. Plaintiff and/or his healthcare providers reasonably relied on Defendants' omissions and representations in using or prescribing the PPI Products, thereby causing Plaintiff to sustain severe and permanent personal injuries. Defendants knew, were aware or should have been aware that their PPI Products had not been sufficiently tested, were defective in nature and/or that their PPI Products lacked adequate and/or sufficient warnings.

390. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

391. Defendants had a duty to provide consumers, patients and healthcare providers with full, complete, accurate and truthful information concerning their PPI Products, including the appropriate use of the product.

392. Defendants also had a duty to disclose material information about serious side effects to consumers such as Plaintiff.

393. By virtue of Defendants' omissions and partial disclosures about the medications, in which Defendants touted their PPI Products as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this Complaint.

394. Plaintiff and/or Plaintiff's healthcare providers reasonably relied on these material misrepresentations and omissions when deciding to prescribe, recommend, purchase and/or consume Defendants' PPIs Products.

395. Plaintiff's healthcare providers were not provided the necessary information by The Defendants to provide an adequate warning to the Plaintiff.

396. Plaintiff was not provided the necessary information by Defendants to provide an adequate warning to the Plaintiff.

397. The PPI Products were improperly marketed to the Plaintiff and/or his healthcare providers as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about the risks associated with PPI use.

398. Plaintiff would not know, in the exercise of reasonable diligence, that Defendants' statements concerning their PPI Products were knowingly and intentionally false and misleading, or that Defendants had not disclosed material facts and information to the Plaintiff and/or the Plaintiff's healthcare providers that would have been material to the choice of treatment.

399. As a direct and proximate result of Defendants' malicious and intentional concealment of material information from Plaintiff and the Plaintiff's healthcare providers, Defendants caused or contributed to Plaintiff's injuries.

400. Prior to the Plaintiff's use of Defendants' PPI Products and during the period in which Plaintiff used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of the drugs, including information regarding increased risk of kidney injuries.

401. Had Plaintiff been aware of the hazards associated with the PPI Products, Plaintiff would have used a safer alternative treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, would not have consumed the PPI Products and/or would have reduced the duration or quantity of use.

402. Defendants' conduct was reckless, willful, wanton, and outrageous, and manifested a reckless indifference for the safety and well-being of patients and consumers, including the Plaintiff.

403. As a direct and proximate result of Defendants' intentional and willful fraudulent concealment of material facts and information from the Plaintiff and Plaintiff's healthcare providers, Defendants caused, and increased the risk of harm of, the injuries and damages suffered by the Plaintiff from the use of Defendants' PPI Products.

404. Had Plaintiff been aware of the hazards associated with PPI use as concealed by Defendants, Plaintiff would have not have accepted PPI treatment and would have accepted a safer and more effective alternative.

405. Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with their PPI Products for the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

406. Defendants conduct is outrageous and shocks the conscience, and knowingly and intentionally placed considerations of financial gain, revenues and profits, market share and marketing advantage over patient safety and well-being.

407. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care. Defendants' conduct, as described herein, was extreme and outrageous.

Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XIV
VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES

408. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

409. Plaintiff used Defendants' PPI Products and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

410. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the consumer protection law, Ohio Rev. Code Ann. §§ 1345.01.

411. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

412. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff,

knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and causes of action, jointly and severally, as follows:

- a. Awarding compensatory damages in excess of \$75,000, including, but not limited to pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life, wrongful death and other noneconomic damages in an amount to be determined at trial of this action;
- b. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;
- c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
- d. Prejudgment interest;
- e. Post-judgment interest;
- f. Awarding reasonable attorneys' fees;

g. Awarding the costs of these proceedings, and

h. Such other and further relief as this Court deems just and proper.

Dated: May 30, 2019

Respectfully submitted,

/s/ John D. Holschuh, Jr.
John D. Holschuh, Jr. (0019327)
Brian P. O'Connor (0086646)
John D. Holschuh III (0095377)
SANTEN & HUGHES
600 Vine Street, Suite 2700
Cincinnati, Ohio 45202
(513) 721-4450 (Telephone)

(s) 852-5994 (Falsimile)
bpo@santenhughes.com
jdh@santenhughes.com
jdhiii@santenhughes.com

-and-

Paul J. Pennock (*Pro hac vice* to be filed)
Paul J. Pennock
Weitz & Luxenberg P.C.
700 Broadway
New York, New York 10003
Phone: (212) 558-5549
Fax: (646)-293-6539
ppennock@weitzlux.com

ATTORNEYS FOR PLAINTIFF

JURY DEMAND

TAKE NOTICE that the Plaintiff hereby demands a trial by jury on all issues triable.

/s/ John D. Holschuh, Jr.
John D. Holschuh Jr. (0019327)

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